# Complete Summary

## GUIDELINE TITLE

Guideline for management of wounds in patients with lower-extremity arterial disease.

## BIBLIOGRAPHIC SOURCE(S)

Wound Ostomy and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity arterial disease. Glenview (IL): Wound Ostomy and Continence Nurses Society (WOCN); 2002 Jun. 44 p. (WOCN clinical practice guideline series; no. 1). [131 references]

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

- Lower extremity ulcers
- Lower extremity arterial disease (LEAD)

### GUIDELINE CATEGORY

Evaluation
Management
Risk Assessment
Treatment

### CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Nursing

Physical Medicine and Rehabilitation
Podiatry

## INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physical Therapists
Physician Assistants
Physicians

## GUIDELINE OBJECTIVE(S)

- To present an evidence-based guideline for the management of wounds in patients with lower extremity arterial disease (LEAD)
- To support clinical practice by providing consistent research-based clinical information with the goal of improved cost-effective patient outcomes as well as to stimulate increased wound research in the areas where there are gaps between research and practice

## TARGET POPULATION

Patients with wounds and lower extremity arterial disease (LEAD)

## INTERVENTIONS AND PRACTICES CONSIDERED

### Assessment

1. Assessment of causative and contributive factors and significant signs and symptoms to differentiate types of lower-extremity ulcers
2. Review of health history (risk factors for lower extremity arterial disease [LEAD], wound history, pain history, pharmacologic history of prescribed and self-prescribed medications)
3. Review of pertinent labs (hemoglobin, hematocrit, cholesterol, triglycerides, prealbumin, albumin, and if patient is on anticoagulants, prothrombin time, and International Normalized Ratio [INR]) to identify risk markers for lower extremity arterial disease
4. Lower-extremity examination (perfusion status, pedal pulses, ankle brachial index [ABI], ankle pressure, toe pressure, angiography, arteriography, assessments for critical limb ischemia and ischemic skin changes, wound characteristics and wound complications)

### Management/Treatment

1. Care guided by a clinical wound expert
2. Wound management (cleaning wounds, debridement, dressing, proper use of antiseptics and topical antibiotics)
3. Monitoring for signs of infection
4. Nutrition (niacin, L-Arginine, nutritional support)

5. Pain management (exercise, spinal cord stimulation, referral for pain management or surgical evaluation as indicated)
6. Management of edema in patients with mixed venous disease and moderate arterial disease (compression bandages, specialist referral as appropriate)
7. Referral, as appropriate, for vascular/surgical evaluation
8. Medications (aspirin to prevent death and disability from stroke and myocardial infarction; cilostazol to improve walking distance of patient with intermittent claudication)
9. Surgical options (bypass surgery/angioplasty, amputation)
10. Adjunctive therapies (hyperbaric oxygen therapy, arterial flow augmentation with intermittent pneumatic compression, growth factors [topical autologous-activated mononuclear cells])
11. Patient education (chronic disease management; smoking cessation; compliance with medications; neutral or dependent position for legs; avoidance of chemical, thermal, and mechanical trauma; routine professional care for toenails, corns, calluses; use of proper-fitting footwear and necessity of wearing socks or hose with shoes; pressure reduction for heels, toes, and other bony prominences; regular follow-ups with healthcare provider)

Note: The guideline developers considered the following measures, however, no recommendations were offered:

1. Nutritional measures to lower cholesterol (vitamin E, garlic and/or fish oil)
2. Prostaglandins (PGE-1 and PGE-2) ciprostine, serotoninergic blocking agents, and pentoxifylline for use in treatment of underlying disease process or resulting ulceration
3. Skin grafts for ulcers in unreconstructed arterial disease

### MAJOR OUTCOMES CONSIDERED

- Risk for and incidence of lower extremity arterial disease (LEAD) and leg ulcers
- Signs and symptoms of LEAD
- Sensitivity and specificity of diagnostic tests
- Pain-free walking and walking distance
- Wound healing
- Complications of LEAD

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The primary authors of this guideline independently conducted a literature search of Medline and Cochrane Library databases to identify studies and systematic reviews published in English from 1980 to 2001. The following medical subject headings (MESH) were used to search for each specific question related to lower

extremity arterial disease (LEAD): arterial disease, arterial insufficiency, peripheral arterial disease, peripheral vascular disease, lower-extremity arterial disease, peripheral arterial occlusive disease, lower-extremity ischemic wounds and ulcers, and critical limb ischemia. The search targeted meta-analyses, randomized controlled trials (RCTs), prospective clinical trials, retrospective studies, and systematic reviews. Bibliographies of selected articles also were reviewed.

## NUMBER OF SOURCE DOCUMENTS

A total of 167 articles were identified and reviewed for this guideline.

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels-of-Evidence Rating

Level I: A randomized controlled trial (RCT) that demonstrates a statistically significant difference in at least one important outcome defined by $p < .05$. A Level I trial can conclude that the difference is not statistically significant if the sample size is adequate to exclude a 25% difference among study arms with 80% power.

Level II: A RCT that does not meet Level I criteria.

Level III: A nonrandomized trial with contemporaneous controls selected by some systematic method. A control may have been selected because of its perceived suitability as a treatment option for an individual patient.

Level IV: A before-and-after study or a case series of at least 10 patients using historical controls or controls drawn from other studies.

Level V: A case series of at least 10 patients with no controls.

Level VI: A case report of fewer than 10 patients.

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not stated

### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

### METHOD OF GUIDELINE VALIDATION

Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The type of evidence (I-VI) and the strength and consistency of evidence grades (A-C) are defined after the Major Recommendations. Citations in support of individual recommendations are identified in the original guideline document.

Assessment of Patients with Wounds and Lower Extremity Arterial Disease (LEAD)

1. Prior to treatment, assess causative and contributive factors and significant signs and symptoms to differentiate types of lower-extremity ulcers, which require varying treatment modalities.
2. Review health history to address: risk factors for LEAD; wound history: pain history, with specific determination of absence or presence of intermittent claudication; rest or nocturnal pain; and pharmacologic history of prescribed and self-prescribed medications.
   Level of evidence = C
3. Review pertinent labs to identify risk markers for LEAD:
   a. Reduced high-density lipoprotein cholesterol (HDL-C).
   b. Reduced plasma subfractions of $HDL_2$-C and $HDL_3$-C. Level of evidence = C
   c. Elevated lipoprotein. Level of evidence = C
   d. Elevated homocysteine levels. Level of evidence = B
4. Conduct lower-extremity examination:
   a. Determine perfusion status by assessing skin temperature, capillary refill, venous refill, color changes, and paresthesias.
   b. Determine presence or absence of pedal pulses. Palpate both dorsalis pedis and posterior tibial pulses. Presence of palpable pulses does not rule out LEAD. Level of evidence = C

c. Measure ankle brachial index (ABI) to assess arterial blood flow in the lower extremities and determine level of ischemia: Normal $\geq$1.0; LEAD = 0.9; borderline is $\leq$0.60-0.8; severe ischemia is $\leq$0.5. (The ABI can be elevated in people with diabetes and those with non-compressible vessels at the ankle.) Level of evidence = B
d. Recheck the ABI periodically (every 3 months) as it may decrease over time.
e. Measure toe pressure (TP) in patients with diabetes in whom LEAD is suspected as those with diabetes may have calcified, non-compressible vessels at the ankle. Toe pressure $\leq$30 indicates LEAD. Level of evidence = C
f. Assess tissue perfusion with transcutaneous oxygen measurement ($TcPO_2$) if ulcer is not healing and ABI is <0.9 or toe pressure <30 mmHg, or if unable to perform ABI or toe pressure because of poorly compressible arteries at the ankle or amputation. $TcPO_2$ <40 mmHg is associated with impaired wound healing. Level of evidence = A
g. Consider angiography or arteriography for all patients with diabetes and nonhealing wounds to rule out significant arterial occlusive disease.
h. Assess for indicators of critical limb ischemia--rest pain requiring analgesics for more than 2 weeks; ankle pressure <40 mmHg, toe pressure <30; tissue loss or gangrene. Level of evidence = C
i. Assess for ischemic skin changes including purpura, atrophy of subcutaneous tissue, shiny, taut skin, hair loss, dystrophic nails.
j. Determine wound characteristics including location, pain, shape and size of wound, wound base, wound edges, periwound skin, exudate, odor or necrosis, or both.
k. Assess for wound complications including cellulitis, gangrene, and osteomyelitis.
l. Consider referral and biopsy for a wound that is atypical in appearance or unresponsive to 2-4 weeks of appropriate therapy.

Interventions for Patients with Wounds and LEAD

1. Recommend patients with wounds and LEAD seek care guided by a clinical wound expert.
2. Relate wound treatments to adequacy of perfusion status.
3. Debridement
    a. Do not debride stable, black eschars until perfusion status is determined. Debridement may be contraindicated in arterial wounds. Level of evidence = C
    b. Cleanse wound with noncytotoxic cleansers.
    c. Provide or consider revascularization and surgical removal of necrotic tissue from an infected wound on an ischemic leg; this is the treatment of choice for limb salvage. Level of evidence = C
    d. Conduct carefully monitored trials of autolytic or enzymatic debridement, if warranted in carefully selected clinical situations in the presence of necrotic tissue.
4. Dressings
    a. Choose dressings for arterial wounds that permit frequent visualizations and inspection of the wound. Level of evidence = C

b. Conduct a carefully monitored trial of moist wound dressings, which may be beneficial for arterial wounds that are open and draining with soft, slough, necrotic material or exposed bones or tendons. Level of evidence = C
c. Maintain dry, stable eschar in noninfected ischemic wounds. Level of evidence = C

5. Antibiotics

   Do not rely on topical antibiotics to treat infected, ischemic wounds. Level of evidence = C

6. Infection
   a. Monitor arterial wounds closely for signs/symptoms of infection, which can be subtle because of reduced blood flow. Level of evidence = C
   b. Immediately refer infected arterial wounds, which are limb threatening, for assessment of perfusion status or surgical intervention, or both. Level of evidence = C
   c. Use tissue biopsy, considered the gold standard, to confirm diagnosis of infection. However, quantitative swab cultures have been demonstrated to be a reasonable alternative in clinical practice in studies not specific to LEAD.
7. Nutrition
   a. Consider niacin; niacin has been shown to increase HDL-C and decrease triglycerides in patients with peripheral vascular disease in oral dosages of 3000 mg/day for up to 60 weeks. Level of evidence = B
   b. Consider L-Arginine oral intake. L-Arginine oral intake of 6.6 g/day for 2 weeks has improved symptoms of intermittent claudication. Level of evidence = A
   c. Provide nutritional support with 2000 or more calories preoperatively and postoperatively, if possible; this has benefited patients undergoing amputations. Level of evidence = C
8. Pain Management
   a. Recommend walking to near maximal pain three times per week. For medically stable patients this has increased pain-free walking and total walking distance for patients with intermittent claudication. Level of evidence = A
   b. Refer for surgical evaluation of reconstructable disease or lumbar sympathectomy in some cases of intractable pain.
   c. Consider spinal cord stimulation for intractable pain in patients with limb ischemia who are unsuitable for reconstruction. Level of evidence = C
9. Management of Edema in Patients with Mixed Venous Disease and Moderate Arterial Disease
   a. Use reduced compression bandages of 23-30 mmHg at the ankle, which may promote wound healing in patients with venous disease and moderate arterial insufficiency (ABI >0.5 to $\leq$0.8). Compression should not be used in patients with ABI <0.5 mmHg. Level of evidence = C
   b. Refer for further evaluation: cellulitis; osteomyelitis; atypical ulcers; intractable pain; absence of both pedal and posterior tibial pulses; ABI <0.9 plus any one of the following--ulcer that fails to improve within

2-4 weeks of appropriate therapy, severe ischemic pain, intermittent claudication; toe pressure <30; ankle pressure <50, ABI <0.5.

c. Give urgent vascular referral for ABI <0.4 or gangrene, or both.

10. Medications
    a. Recommend aspirin in doses of 75-325 mg oral/day. This is recommended for patients in general (not specific to LEAD) to prevent death and disability from stroke and myocardial infarction. Level of evidence = C
    b. Administer cilostazol, 100 mg, twice a day, orally; it may improve walking distance of patient with intermittent claudication. Level of evidence = A
11. Surgical Options
    a. Carefully assess risks versus short- and long-term benefits of bypass surgery/angioplasty. Short-term benefits may not be sustained long term. Level of evidence = A
    b. Assess preoperative amputation $TcPO_2$ levels. Pre-operative levels greater than 20 mmHg are associated with successful healing after amputation. Level of evidence = A
12. Adjunctive Therapies
    a. Consider hyperbaric oxygen therapy, which may benefit patients with ischemic ulcers. Level of evidence = B
    b. Consider intermittent pneumatic compression, which may benefit individuals with intermittent claudication and limb threatened arterial disease in whom vascular reconstruction is not feasible. Level of evidence = B
    c. Consider topical autologous activated mononuclear cells, twice per week, which may enhance healing of ischemic ulcers. Two intra-arterial basic fibroblastic growth factor doses 30 micrograms/kg, improved calf flow in patients with LEAD. Level of evidence = B
13. Patient Education
    a. Teach patients with LEAD about: chronic disease management; compliance with medications; neutral or dependent position for legs; avoidance of chemical, thermal, and mechanical trauma; routine professional nail and footcare; use of proper fitting shoes and footwear; wearing socks or hose with shoes; pressure reduction for heels, toes and other bony prominences; need for regular follow-up with healthcare provider.
    b. Recommend smoking cessation, which slows progression of atherosclerosis and decreases risk of cardiovascular events/death. Level of evidence = B

Definitions:

Levels-of-Evidence Rating

Level I: A randomized controlled trial (RCT) that demonstrates a statistically significant difference in at least one important outcome defined by $p < .05$. A Level I trial can conclude that the difference is not statistically significant if the sample size is adequate to exclude a 25% difference among study arms with 80% power.

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Level III: A nonrandomized trial with contemporaneous controls selected by some systematic method. A control may have been selected because of its perceived suitability as a treatment option for an individual patient.

Level IV: A before-and-after study or a case series of at least 10 patients using historical controls or controls drawn from other studies.

Level V: A case series of at least 10 patients with no controls.

Level VI: A case report of fewer than 10 patients.

Rating of Evidence

Level A: Two or more supporting RCTs on lower extremity arterial disease (LEAD) in humans (at Levels I or II), meta-analysis of RCTs, or Cochrane Systematic Review of RCTs.

Level B: One or more supporting controlled trials on lower extremity arterial disease in humans or two or more supporting trials in an animal model (at Level III).

Level C: One supporting controlled trial, at least two supporting case series that were descriptive studies on humans, or expert opinion.

### CLINICAL ALGORITHM(S)

An algorithm is provided for the differentiation of wound etiology.

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations. Where a level of evidence rating is not included, the information presented represents a consensus of the panel members.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Identification of patients with arterial insufficiency who are at risk for developing wounds
- Identification of patients whose current wounds are caused or complicated by arterial insufficiencies
- Implementation of appropriate strategies and plans may aid in:
    - Attaining/maintaining intact skin
    - Pain reduction
    - Prevention of complications
    - Prompt identification and management of complications
    - Optimizing the potential for wound healing

- Limb preservation
- Involvement of patients and caregivers in self-management

### POTENTIAL HARMS

- Wounds treated with topical antibiotics may develop resistant organisms over time.
- Topical creams, ointments, and gels containing antibiotics may cause sensitivity reactions.
- Debridement of stable eschars from wounds associated with severe or critical ischemia may lead to bacterial overgrowth, infection, and loss of limb.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Wound Ostomy and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity arterial disease. Glenview (IL): Wound Ostomy and Continence Nurses Society (WOCN); 2002 Jun. 44 p. (WOCN clinical practice guideline series; no. 1). [131 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2002 Jun

### GUIDELINE DEVELOPER(S)

Wound, Ostomy, and Continence Nurses Society - Professional Association

## SOURCE(S) OF FUNDING

Ortho-McNeil Pharmaceutical, Inc. provided partial support for the development of the Wound, Ostomy, Continence Nurses (WOCN) Society guidelines through an unrestricted educational grant.

## GUIDELINE COMMITTEE

Wound, Ostomy, Continence Nurses (WOCN) Lower-Extremity Arterial Disease Panel

Wound Guidelines Task Force

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the guideline panel submitted a Conflict of Interest Disclosure Form, which was reviewed by the WOCN Executive Director, who determined that no conflict of interest exists with any individual panel member.

Members of the WOCN Society Council, the WOCN ad hoc Ethics Committee, and the Journal of Wound, Ostomy and Continence Nurses Society Editor receive no compensation from companies that provide products or services related to the

practice of WOC(ET) nursing or from firms that provide services to the WOCN Society.

## GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

## GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase ($15 nonmembers; $10 members) from the Wound Ostomy and Continence Nurses Society (WOCN), 4700 W. Lake Avenue, Glenview, IL 60025-1485; Web site: www.wocn.org. Orders can be placed via telephone at (888) 224-9626 or by fax at (866) 615-8560.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI on December 13, 2002. The information was verified by the guideline developer on January 13, 2003.

## COPYRIGHT STATEMENT



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